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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Brian A. Rosenfeld, M.D. and Michael Breslow, M.D.

Serial No.: 09/443,072 Group Art Unit: 2167

Filed: 11/18/99 Examiner: Harle, J.

For: **SYSTEM AND METHOD FOR PROVIDING CONTINUOUS, EXPERT NETWORK CRITICAL CARE SERVICES FROM A REMOTE LOCATION(S)**

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AFFIDAVIT BY DR. JAMES SHAFFER

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I, Dr. James Shaffer, residing at 200 East Sheridan Road, Suite I Melbourne, FL 32901-3182 state as follows:

1. I obtained my Medical Degree in Medicine in 1992 from The Ohio State University

2. My experience includes Critical Care Medicine; 8 years

3. My Curriculum Vitae is attached to provide further information regarding my background and qualifications that allow me to make the statements contained herein.

4. I have read and reviewed Patent Application Serial No.: 09/443,072 and the following U.S. Patents (collectively, the "Patent References"):

- U.S. Pat. 6,364,834 issued to Reuss, et al. entitled Method and System for Remotely Monitoring Multiple Medical Parameters in an Integrated Medical Monitoring System," (herein, the "Reuss Patent").
- U.S. Pat. 4,838,275 issued to Lee entitled, "Home Medical Surveillance System," (herein, the "Lee Patent").
- U.S. Pat. 3,646,606 issued to Buxton et al. entitled, "Physiological Monitoring System," (herein, the "Buxton Patent").

5. The Reuss Patent describes an integrated medical monitoring system having a patient monitor, a central monitor, and a remote access device. Each of these devices is tied together through an integrated communications link. The communications between various

components of the system are bi-directional, an attribute described as affording the opportunity to establish monitoring parameters from remote locations, provide interactive alarms and monitoring capabilities, and provide data exchange between components of the system. The thrust of the Reuss Patent is the collection of data from monitors so that the data are *available* to a caregiver. The caregiver may view the data on a display or request the data for viewing.

The claimed inventions, as noted in the claims of the Rosenfeld/Breslow patent application, provide for 24-hour dedicated monitoring/management system and method that monitors and processes clinical data in a fashion germane to an intensivist-led care team, made up of intensive care specialists, critical care nurses and clerical support personnel, to care for patients in multiple ICU's in disparate geographic locations, either within a building or in different buildings, simultaneously and continuously. The claimed inventions facilitate the provision of patient care by a care team from a dedicated monitoring facility comprising equipment and decision support algorithms developed explicitly for this purpose. The claimed invention provides for automated warnings relating to threshold vital signs and trends in vital signs and other physiologic and laboratory data, provides assessment of those thresholds and trends for the intensivist, and makes recommendations for intervention available for consideration by the intensivist. The thresholds and trends are pre-set based upon admitting and daily diagnoses and are customizable based upon the particular patient and condition. The claimed inventions thereby relieve the care team of having to sort and deal with large volumes of unprocessed clinical and patient data.

In contrast to the present invention, the Reuss Patent describes detecting when data has been read, and characterizes this function as "particularly useful in time-sensitive medical emergency situations." (See, Col. 6, line 5-9). The claimed invention treats all data as time-sensitive. While the Reuss Patent describes automation of data acquisition, the analysis of the transmitted data is performed post hoc and by a caregiver. Additionally, the Reuss Patent contemplates that intervention may not, in fact occur. One of the described capabilities of the Reuss invention is the ability to "determine the location of a plurality of caregivers and select an appropriate primary recipient of the alarm message based on location." Reuss Patent, col. 5, lines 47-49. This suggests that while patient data is acquired, it may not be acted upon. This reading is bolstered by references to the bi-directional capabilities of the communications link, "which can determine that a caregiver has read and responded to a message." Reuss Patent, col.

5, lines 3-5.

It is clear that the Reuss Patent is directed to information gathering, distribution and ad hoc evaluation, not to the automated proactive monitoring and intervention of the claimed inventions. Rather, the Reuss Patent teaches observation of patients by a caregiver and evaluation of data directly by a caregiver, rather than easing that burden through knowledge based means.

6. The Lee Patent describes an apparatus for use in a patient's home that includes special furniture on which the patient lies and sits. Embedded in this special furniture are devices that automatically sense multiple parameters related to the patient's health. The patient cooperates only passively. The parameters are so chosen to provide a profile of the patient's general state of health. The apparatus also generates electronic health-parameter signals related to the sensed parameters, and it transmits these signals from the patient's home to a central surveillance and control office. Equipment there receives the signals, displays corresponding indicia of the parameters, and transmits control signals back to the patient's apparatus. Two-way voice communication between the patient and a highly trained observer at the central office supplements the electronic measurements. The observer conducts routine diagnostic sessions except when an emergency is noted from these sessions or from a patient-initiated communication. The observer determines whether a non-routine therapeutic response is required, and if so facilitates such a response such as a transfer to a hospital for more direct care. Selection among emergency cases follows a highly refined emergency-priority hierarchy.

The Lee Patent is directed to monitoring **ambulatory patients** in a home environment. However, this monitoring is not stated to be continuous. Rather, the control office is described as having means for selecting a particular one of the patients for display of that particular patient's indicia by a displaying means. These selecting means are manually operable by a trained observer in the office. In this system the trained observer is enabled to determine the general state of health of substantially each one of the many patients--and also to determine from this information whether a non-routine therapeutic response should be provided for substantially each patient. An emergency-priority hierarchy guides the observer in a systematic way when the observer must select, from among two or more patients requiring emergency attention, which patient to deal with first, which next, and so on.

This hierarchical approach to "monitoring" is distinct from the 24-hour, continuous care

provided by the claimed inventions. The system of Lee is only intended to monitor a single patient at a time, as is typically done by physicians with outpatients. It is inconceivable that a single observer, whether a doctor or a trained intensivist, can provide quality care to plurality of acutely ill patients, such as those found in an ICU, if that same observer is charged with monitoring data streams and evaluating the data for patterns indicative of clinical changes in the condition of each of the plurality of patients.

The teachings of Applicant's disclosure challenge this old regime by providing automated tools that continuously receive the data collected from an acutely ill patient, correlate disparate physiological indicators, and apply algorithms to determine if the present and projected condition of the patient warrants proactive intervention.

7. The Buxton Patent describes an apparatus for measuring physiological parameters indicative of the condition of a patient and sending those parameters to a central monitoring station. The central monitoring station would display the parameters in analog and digital form issue an alarm signal in the event certain parameter values are detected. Viewing patient data is accomplished by selecting a patient using a switch (Figure 3, callout 122). Thus, not all patients are monitored at all times. The Buxton Patent is clearly directed to a data gathering system combined with a single event driven process to manage "emergencies." Data is presented to a single operator and, except for certain alarm conditions, the evaluation of that data is charged to the single operator. Applicant further submits that it is not possible for a single operator to make simultaneous, continuous, proactive evaluations of multiple patients in real-time using the system and methods taught by Buxton. Indeed, the Buxton Patent merely subscribes to the ordinary monitoring paradigm employed presently in the majority of hospitals.

By contrast, the claimed inventions are directed to systems and methods for providing care to each patient in an ICU simultaneously on a 24-hour basis.

8. Even assuming that one skilled in the art were motivated to combine the references as suggested by the examiner, regardless of the how the references are combined, the combination will not successfully produce the results of the claimed inventions. Application of the present invention gave unexpected results with respect to patient mortality rate, length of stay, average case cost, average case contribution to margin, and monthly contribution to margin as well as extending the typical 1:12 ratio of intensivists to patients to a ratio of 1:33 in one published study and as high as 1:83 in current practice.

(a) Application of the present invention to the monitoring of a plurality of hospital ICUs resulted in a 27.1% decrease in mortality (from 12.9% to 9.4%) relative to a baseline that *included intensivists*. Although it is known that the participation of an intensivist can decrease the ICU mortality rate, it was unexpected to one of ordinary skill in the art that the addition of the remote monitoring and proactive processing of clinical data of the present invention to such ICUs would result in a further 27% decrease in mortality.

(b) Application of the present invention also decreased the average length of stay (LOS) in the study ICUs by 16.6% (from 4.35 days to 3.63 days). This decrease in LOS is significant given the increasing need for ICU beds and the solution presented by the present invention is non-obvious since many ICUs operate at full capacity, thereby requiring many acutely ill patients to be treated elsewhere in the hospital. Hospitals would surely have implemented such an improvement in throughput/capacity *if it had been obvious.*

(c) Application of the present invention also resulted in a significant decrease in the average case cost an ICU stay by 24.6%, a significant (55.7%) increase in the average case contribution margin, and a significant (65.9%) increase in the contribution margin per month. All of these saving and cost related factors are important since they enhance the ability of hospitals to provide ICU care and extend a resource that is predicted to be stretched thin. Further, any such significant cost-saving measure would have surely been implemented by hospitals *if it had been obvious*.

9. As stated above, it has been recognized that the participation of an intensivist can greatly improve ICU care. The currently recommended ratio of intensivists-to-patients is between 1:12 (multi-patient type unit) and 1:15 (single-patient type unit). Despite the knowledge that ICU care can be improved with intensivists, the current intensivist-to-patient ratio has prevented wide adoption of the recommendation due to a lack of trained personnel. Application of the present invention has addressed long-felt but unresolved needs. That is, application of the present invention decreased mortality, LOS, and costs *while at the same time extending the intensivist-to-patient ratio by greater than 500% to 1:33- 1:83*, thereby greatly assisting in the unresolved need for more intensivists by potentially more than tripling patient access to intensivist-supervised care.

10. I believe that remote, 24-hour monitoring of ICU patients in multiple geographically disparate locations in a manner germane to an intensivist-led care team is not taught by any of the aforementioned Patent References nor would one of skill in the art make the required changes to the equipment and procedures disclosed in the Patent References to arrive at the present invention for at least the following reasons:

- The Patent References share the belief that if only physiological data can be delivered to the right person, the health of patients would be improved. Thus, each addresses means for gathering physiological data and distributing that data to a location or locations. This is a data-gathering paradigm that makes data available to experts. While the inventions may offer solutions to the problems set forth above, the references teach little more than extending the basic bedside monitoring and data collection to remote locations.
- Determining that an emergency has occurred based on the preset threshold of a single physiological parameter and issuing an alarm is an event-driven process, and is the current bedside model, not a "proactive" one. Knowing that a patient has entered an emergency state is not the same as "knowing" that a patient is entering an emergency state at some point in the future if some proactive intervention is not initiated. Further, using trending data that is acquired and saved over hours of monitoring time does not qualify as proactive. The proactive aspects of the claimed inventions envision real-time, continuous *analysis* of data on a 24-hour, 7-day per week basis.
- The invention described and claimed in Application Serial No.: 09/443,072 does not rely on the paradigm of primary monitoring by bedside personnel, with secondary calls to intensivist, but rather provides parallel processing of data in a continuous, 24-hour care of each ICU patient. The claimed inventions facilitate proactive care of these patients by providing means by which a care team may unilaterally enter a patient's room for video and audio communication. Indeed, the high fidelity video facilitates the real time intervention supported by the claimed invention by allowing the intensivist to make a better determination of the patient's status. Using decision support algorithms, the systems and methods of the claimed inventions automatically issue alerts when a patients' vital signs or laboratory values indicate a detrimental trend and facilitate interventions with the patient when necessary. The Patent

References neither teach 24-hour monitoring and proactive processing and analysis of the monitored clinical data by an intensivist-led care team nor the use of decision support algorithms to alert the intensivist of a detrimental trend in a patient's vital signs.

- Even assuming that one skilled in the art were motivated to combine the references as suggested by the examiner, regardless of the how the references are combined, the combination will not successfully produce the results of the claimed inventions. This statement is supported, if not proven, by the dramatic and unexpected results derived from practicing the teachings of Applicants disclosure as describe above.

Date: 2/19/04

James P. Shaffer, M.D.
Director, Adult ICU Service, Health First, Inc
Rockledge, Florida
Title
Affiliation

WITNESS MY HAND and seal this 19th day of February, 2004.

James P. Shaffer, M.D., FCCP
Type Name Here

STATE OF Florida)
) ss:
COUNTY OF Brevard)

James Shaffer

On this 19th day of February, 2004 personally appeared before me _____ to me known, and known by me to be the same person described in and who executed the foregoing instrument, and acknowledged that he executed the same, of his own free will and for the purposes set forth.

Sara R. Gibson
Notary Public

My Commission Expires: 10/9/2004

SARA R. GIBSON
Notary Public, State of Florida
My comm. expires Oct. 9, 2004
Comm. No. CC973985

CURRICULUM VITAE

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Other Employment

Medical Director, Adult ICU Services
Holmes Regional Medical Center
July 15, 2002

Medical Director
Health First Sleep Disorders Center
August 1, 2001

Education

The Ohio State University Medical Center
Columbus, Ohio
Chief Medical Resident
Department of Internal Medicine
1998-1999

The Ohio State University Medical Center
Columbus, Ohio
Fellow, Pulmonary and Critical Care Medicine
1997-2000

The Ohio State University Medical Center
The Columbus Children's Hospital
Columbus, Ohio
Internal Medicine/Pediatrics Residency
1992-1996

The Ohio State University College of Medicine
Columbus, Ohio
Doctor of Medicine, June 1992

Education- cont'd

Malone College
Canton, Ohio
Bachelor of Arts [chemistry]
April 1988, *cum laude*

Board Certification and Licensure

National Board of Medical Examiners
Part I 1990
Part II 1991
Part III 1993
The American Board of Internal Medicine
October 6, 1996 No. 060237
The American Board of Pediatrics
November 1, 1996 No. 173324
Ohio License #35-06-5341
Florida License # ME 79932
The American Board of Internal Medicine/Pulmonary Diseases
January 21, 2000
The American Board of Internal Medicine/Critical Care Medicine
January 9, 2001
The American Board of Sleep Medicine
April 8, 2002

Professional Organizations

Society of Critical Care Medicine, 1996-present
American Thoracic Society, 1996-present
Fellow, American College of Chest Physicians, November 2000

Honors and Awards

Alpha Omega Alpha
Outstanding Teaching Resident Award, The Ohio State University, Department of Internal Medicine, 1995
Outstanding Teaching Resident Award, The Ohio State University, Department of Pediatrics, 1996
Outstanding Senior Resident Award, The Ohio State University, Department of Internal Medicine, 1996
1997 Resident Teaching Award, The Ohio State University College of Medicine Class of 1997

Service

Volunteer, Habitat for Humanity, 1986
Coordinator, Concerns and Referral Extension, 1989
Volunteer, Cystic Fibrosis Foundation, 1990
Housestaff Advisory Committee, 1993
Outpatient Clinic Advisory Committee, 1994

Additional Coursework

Advanced Cardiac Life Support Instructor 1998
Advanced Cardiac Life Support 1996
Pediatric Advanced Life Support 1996
Fourth Charleston Pulmonary Symposium 1995
Managing Risk in Emergency Medicine 1997
American College of Chest Physicians 1997
American Thoracic Society/American Lung Association International Conference 1998
American Thoracic Society/American Lung Association International Conference 2000
American College of Chest Physicians 2000
Atlanta School of Sleep Medicine
Part I Review Course, September 2000
Part II Review Course, March 2001
The School of Sleep Medicine
Part II Review Course, February 2002

Interventional Bronchoscopy

- Endobronchial Stent Placement (~30)
  - Ultraflex
  - Rousch-Y
- Cryotherapy
- Electrocautery
- Endobronchial repair of broncho-pleural fistula (~7)

Publications

Refereed Journals

Shaffer JP, Barson W, LuQuette M, Groner JI, Hogan MJ, Allen E. Massive Hemoptysis as the Presenting manifestation in a child with Histoplasmosis. *Pediatric Pulmonology* 1997;24:57-60.

Shaffer JP, Allen JN, The Use of Expandable Metal Stents to Facilitate Extubation in Patients with Large Airway Obstruction. 1998. *Chest* 114 1378-1382.

Abstracts

Shaffer JP, Allen JN, The Use of Expandable Metal Stents to Facilitate Extubation in Patients with Large Airway Obstruction. 1997. *Chest* 112(3):25S.

Shaffer JP, Allen JN. Complications and Success Rates of Three Metal Stents. *Amer J Resp Crit* Care Med. 2000; 161(3):A234S.

Shaffer JP, Allen JN, Prior, RB. Detection of Endotoxin in Talc Preparations Used for Pleurodesis. *Chest 118(4);130S*

Oral Presentations

Outcomes of Four Types of Flexible Metal Airway Stents. Fellows Research Conference. The Ohio State University Medical Center. May 2000. *[~60 attendees]*

Outcomes of Four Types of Flexible Metal Airway Stents. Poster presentation at The American Thoracic Society International Meeting. Toronto, Canada. May 2000.

Update on Thromboembolic Disease. VA Medical Center, Chillicothe, Ohio. May 2000. *[~20 attendees].*

Lung Disease: Evolving Concepts and New Management Strategies. American Medical Writers Association. March 2000. *[~25 attendees]*

Pulmonary Thromboembolic Disease: Current Concepts on Diagnosis, Management, and Etiology. Pediatric Grand Rounds. The Columbus Children's Hospital. September 1999. *[~175 attendees]*

IV Linezolid for the Treatment of Nosocomial Pneumonia. Pulmonary Research Conference. The Ohio State University Medical Center. August 1999. *[~ 25 attendees*]

Pulmonary Thromboembolic Disease: Answers to the Tough Questions. Internal Medicine Grand Rounds. The Ohio State University Medical Center. February 1999. *[~150 attendees]*

Congenital Heart Disease in the Adult. Internal Medicine Grand Rounds, The Ohio State University Medical Center, June 1996. *[~150 attendees]*

Acute Cyanide Poisoning. Pulmonary Grand Rounds, The Ohio State University Medical Center, April 1996. *[~50 attendees]*

Inhalational Chemotherapy: Investigation of a New Delivery Modality for the Treatment of Metastatic and Primary Lung Malignancies. Pulmonary Research Conference, The Ohio State University Medical Center, October 1997. *[~25 attendees]*

The Use of Expandable Metal Airway Stents to Facilitate Extubation in Patients with Large Airway Obstruction. American College of Chest Physicians Meeting, New Orleans, October 1997. *[~150 attendees]*

Pulmonary Amyloidosis. Pulmonary Grand Rounds, The Ohio State University Medical Center, November, 1997 *[~50 attendees]*

Detection of Endotoxin in Talc Used for Pleurodesis. American College of Chest Physicians Meeting, SanFrancisco, October 2000. *[~100 attendees]*

Management of Large Airway Obstruction Space Coast Cardiopulmonary Conference, Cocoa Beach, Florida September 2001 *[~225 attendees]*

Update on The Acute Respiratory Distress Syndrome Space Coast Cardiopulmonary Conference, Cocoa Beach, Florida August 2002 *[~225 attendees]*

Emerging Concepts in the Management of Sepsis, Holmes Regional Medical Center. June 2003. *[~75 attendees]*

Emerging Pathogens in the ICU, Vero Beach, Florida June 2003 *[~10 attendees]*

Smart Systems Saving Lives, Holmes Regional Medical Center, Melbourne, Florida September 2003 *[~60 attendees]*

Personal

Born September 27, 1966, Youngstown, Ohio
Columbus Marathon 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997,1998
Cleveland Marathon 1991, 1995
Boston Marathon 1992, 1996, 1997, 1998, 1999
Toledo Marathon 1996
Pittsburgh Marathon 1993
Disney Marathon 2000
Chicago Marathon 2001, 2003
First Degree Blackbelt 1988

Rev October 2003